

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, DC 20460



OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES  
Antimicrobials Division

October 2, 2003

SUBJECT: FIFRA 6(a)(2) Incident Report  
Lysol Brand Disinfectant S.A. Cleaner

DP Barcode: 293382  
Manufacturing-use [ ]

OR

Reg. No. Or File Symbol: 675-55  
End-use Product [X]

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RM Branch II

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Product Formulation  
Active Ingredient(s)

% by wt.

Citric acid.....	2.5%
Other ingredients.....	97.5%
Total.....	100%

Background:

The registrant has submitted a laboratory report of failed confirmatory efficacy testing for the effectiveness of this disinfectant and cleaning product against *Mycobacterium bovis*, BCG which is used as a surrogate for *Mycobacterium tuberculosis*. The report was contained in one document, MRID No. 459180-01.

### Summary of test results:

1. The testing was conducted using the Association of Official Analytical Chemists (AOAC) Tuberculocidal Activity Method (Confirmative In Vitro Test for Determining Tuberculocidal Activity) (DIS/TSS-6 Supplemental Efficacy) by MicroBioTest, Inc, Sterling, Va. An acceptable test should show no growth on any of the carriers. The first test was set up January 6, 1998 using Formula 167, Lot #432-172A and Lot #432-172B. Ten carriers were used for each lot of product in the initial testing procedure. Carriers were incubated until April 6, 1998. Growth in tubes were confirmed by acid-fast staining of each positive tube. The organisms were consistent with the challenge organism. To confirm the failure of the product to perform as expected, a repeat efficacy test, using the same procedure but with the modification of using twenty carriers/product lot, was set up April 22, 1998. The final results are listed in the tables below.

Test #1 January 6, 1998 Results Expresses as No. of Positive Tubes/Total Number of Tubes

Test Material Lot	No. of (+) Carriers/Total No of Carriers
Lot 432-172A	3/10
Lot 432-172B	2/10

Carrier Counts. Results Expresses as Colony Forming Units (CFU) Recovered/Carrier

Carrier Replicate	CFU/carrier recovered	Average CFU/Carrier
1	$1.2 \times 10^5$	$1.3 \times 10^5$
2	$1.3 \times 10^5$	
3	$1.3 \times 10^5$	

All controls for neutralization effectiveness, sterility, and viability met the criteria for a valid test

Test #2 April 22, 1998 Results Expressed as Number of Positive Tubes/Total No. Tubes

Test Material Lot No.	No. (+) Tubes/Total no. Tubes
Lot 432-172A	4/20
Lot 432-172B	17/20

Carrier Counts Results Expressed as Colony Forming Units (CFU) Recovered per Carrier

Carrier Replicate	CFU/carrier recovered	Average CFU/carrier
1	$1.2 \times 10^5$	$1.3 \times 10^5$
2	$1.3 \times 10^5$	
3	$1.3 \times 10^5$	

Comments and Recommendations:

1. The label lists a claim for the effectiveness of this product as a tuberculocide. This study does not support that claim. A review of the product file indicates that the registrant submitted a subsequent study of confirmatory efficacy data (MRID No. 448884-03) conducted by ViroMed Laboratories, St. Paul, MN in November 1998 which demonstrated the product's effectiveness against *Mycobacterium bovis* BCG when tested in the presence of 5% organic soil for 10 minutes at 20°C. Thus, the label claim is valid, and does not have to be removed.